EXHIBIT B

Report of the Review of Various Documents Relating to Actavis and to the Actavis Product Digitek which is Digoxin.

Other company names and other products are mentioned in the documents provided.

For:
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By:
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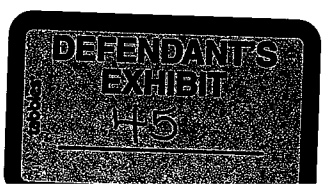
June 14, 2010

SMART CONSULTING GROUP LLC



Expert Report of James J. Farley
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Report concerning Actavis
and its various Northern New Jersey locations and its Digitek Product.

For:
Mr. Peter Miller
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This report consists of the following sections:

1. Qualifications and Background
2. How the FDA Inspects a Pharmaceutical Company. The Purpose and Nature of Food and Drug Administration Inspections.
3. Documents Reviewed by JJF
4. Additional Reference Sources
5. Comments
6. Conclusions

1. Qualifications

I am a chemist with more than forty years experience in the pharmaceutical industry working for pharmaceutical firms, a pharmaceutical package component supplier, the United States Food and Drug Administration (FDA), and for the last fourteen years as a consultant to the industry. This background provides three distinct points of view of the pharmaceutical industry and its regulations. Details are in my Curriculum Vitae which is Attachment A to this report.

A- Pharmaceutical Industry – As a research chemist I had to be knowledgeable of, and in compliance with, FDA regulations.

B- Pharmaceutical Package Component Producer – I held various positions ranging from Supervisor, Quality Control, to Director, Research & Development. I had to be knowledgeable of, and in compliance with, FDA regulations since our customers were the pharmaceutical firms. Our products, primarily rubber stoppers, had direct contact with drug preparations.

C- FDA – During my time with the FDA in Philadelphia:

I analyzed new and existing pharmaceutical compounds and preparations.

I participated in inspections of firms and in the preparation of Establishment Inspection Reports (EIRs) and 483s. A form 483 contains a list of "Observations," which are violations of regulations.

I directed the activities of a thirty member laboratory staff in analyses of products and in accompanying Investigators on inspections.

I worked at FDA Headquarters for a 30 day detail as Acting Deputy Director, Division of Field Science, during which I interfaced with several FDA Headquarters areas.

At times, when the Philadelphia District Director would be out of the office for a few days, I was Acting District Director, in which capacity I issued Warning Letters and performed many other duties.

For a period of a month, I directed the activities of the Investigations Branch in addition to directing the Science Branch. That is, I was Director of the Science Branch and Acting Director of the Investigations Branch at the same time. This was until a replacement for the promoted and transferred former Director of the Investigations Branch was selected.

I prepared and delivered training courses for FDA staff explaining the pharmaceutical industry and how products are made.

D- Consultant – As a pharmaceutical and FDA regulatory consultant I assist clients in the following areas:

Food and Drug Administration Compliance

- Quality Audits and Implementation of Changes
- Establish/Review Quality Assurance Procedures and compliance with GMPs, including GLPs
- Prepare the Chemistry, Manufacturing, and Controls section of a New Drug Application (CMC section of NDA)
- Prepare Drug Master Files (DMFs)
- Prepare firms for Pre-Approval Inspections (PAIs)
- Process Validation
- Establish program for Corrective Action; Preventive Action (CAPA) including Root Cause Analysis (RCA)
- Establish system for Out-of-Specification (OOS) results and for Deviations
- Consult/assist in responses to FDA Warning Letters
- Consult/assist in responses to FDA form 483s

Technical

- Laboratory Procedures — Development and Validation
- Package/Product Compatibility
- Selection and Testing of Rubber Stoppers and Plastic and Glass Components

Management

- Laboratory Management
- Work Flow Design
- Strategic Planning
- Establish responsibilities and performance criteria for contractor organizations

Training — Design and present training programs in the following:

- Corrective Action; Preventive Action (CAPA)
- Good Manufacturing Practices (GMPs)
- Leadership skills for new managers
- Preparation for an FDA inspection — GMP or Pre-Approval

Background
I am being paid $150/hour from the Smart Consulting Group. I do not know what fee structure Smart Consulting Group has with our client. When on contract with a large firm I accept this instead of the $200/hour usual fee since they have obtained the project and they do the billing.

In the last four years my previous depositions were for:
1- Mainor Eglet Cottle LLP in Las Vegas, Nevada. Deposed in Las Vegas, February, 2010. Henry Chanin, et al. v. Desert Shadow Endoscopy Center et al. Other defendants were Teva and Baxter pharmaceutical companies. Case number 08A571172. Clark County Courts. Eighth Circuit Court of Nevada.

2- Connelly Law in Tacoma, Washington. Deposed in Savannah, Georgia, April 2008. Angela Olson, Plaintiff, vs Septodont, Inc., Burkhart Dental, Inc., Reeve Burkhart Dental Supply Company, Burkhart Dental Supply Company, and John Does 1-5. In The Superior Court of the State of Washington No. 06-2-10742-5 for Pierce County.

I have provided several Subject Matter Expert reports but provided only the depositions above in the last 4 years.

2. How the FDA Inspects a Pharmaceutical Company. The Purpose and Nature of Food and Drug Administration Inspections.

A pharmaceutical company's goal is to produce quality products that will help persons to maintain or regain health. It reinvests the earnings from its sales to continue producing quality drugs for the consumers/patients. The goal of the FDA is to "Protect the Consumer." That is to say that the goal of the FDA is not to help the pharmaceutical company to make a good product but rather to ensure that the firm does not make an ineffective or unsafe product. Note that these

goals are not the same and neither are they opposed. They can be considered synergistic with regard to the safety of the public.

The regulations are contained in The Federal Food, Drug, and Cosmetic Act.
The rules applying to drug firms are listed in Title 21 of the Code of Federal Regulations, parts 210 and 211. This is written as 21 CFR 210 and 211. It contains the information on how to comply with Good Manufacturing Practices (GMPs).

Any drug or drug product component manufacturer must comply with these regulations.
The FDA, in exercising its oversight, does this by periodic inspections. On the one hand, if the FDA never inspected firms at all and simply accepted a company's word that they have been doing things right, there would be no oversight. On the other hand, to have an FDA person present at a particular firm every day would also not be appropriate. The solution to ensuring that the drug firms are complying with the regulations is to conduct periodic inspections of the firms. This is done by one or more Consumer Safety Officers, also called Inspectors, usually accompanied by one or more FDA scientists.

In a GMP inspection the FDA team leader will show the person at the pharmaceutical facility a Form 482 which is a notice of inspection. FDA persons' credentials will be shown. The leader will ask to see the highest ranking person at the facility. Usually a conference room discussion about the management responsibilities, including presentation of an organization chart, follows the introduction. Some firms have prepared slide presentations and binder packages of diagrams and data ready to present to interested parties including the FDA. Next, a tour of the facility is in order. After that, the detailed inspection begins.

The areas covered in the inspection include, but are not limited to, the following:

- Overview of Operations
- Organization and Responsibilities of persons
- Facility tour
- Incoming materials - receipt, inspection, handling, storage, and testing
- Manufacturing, including work-in-progress testing
- Packaging
- Finished goods release testing
- Stability Program for storage and testing of raw materials and finished products
- Validation program - for tests and processes
- Quarantine/reject process
- Line clearance/reconciliation between production runs
- Finished goods inspection/release
- Internal audit program
- Calibration of instruments and equipment and the calibration logs
- Deviation and Out-of-Specification (OOS) Investigation procedures - that is, the Corrective Action; Preventive Action (CAPA) program
- Change control
- Training and the training records
- Batch control management
- Customer complaints

- Adverse Event investigation and reporting system
- Control of specifications

The categories listed above will serve to illustrate many of the areas that must be functioning properly to ensure that the pharmaceutical product is, as FDA requires, of the correct "Identity, Strength, Quality, and Purity."

There are cases where firms are in complete compliance and there are firms where the systems and procedures are not in place. Then there are those firms where the systems and procedures are in place but there is no adherence to them. The inspection reveals what is actually happening at any particular pharmaceutical company.

At the conclusion of an inspection an Establishment Inspection Report (EIR) is written. That can be compared to a trip report in industry. If all is well at the inspected firm then the EIR is sufficient. If there have been "Observations," which are violations, contained in the EIR, they are listed in a separate document. That is the "483" - named because the observations are written on the FDA form 483. Examples of the observations are provided on the form. The persons at the firm at told of these during the exit meeting and are informed that a typed version of the 483 will be sent in the mail to them. They are actually aware during the course of the inspection, since some of the firm's personnel accompany the FDA persons during the inspection.

With the issuance of the 483, the firm is expected to correct the violations promptly. Almost invariably, the firm will respond in writing providing a time frame for when the corrections will be made. The firm will also be placed on the FDA schedule for another inspection to verify that the changes have been made.

If the changes have not been made in a reasonable time period, then a Warning Letter may be issued. This is a stronger indication of the severity of the situation. While it is prudent to respond to a 483, it is imperative to respond to a Warning Letter within 15 days.

If the firm is still not compliant then an Injunction may be requested and issued. In the case of a Consent Decree, the firm is being told by the court that they "[author's words] are not good enough to make a quality product; however, if that product is needed in the market, they must hire outside experts – consultants – to work at the firm and verify each batch of the product, until the FDA agrees that the company is able to produce the products of the correct Identity, Strength, Quality, and Purity themselves." Consent Decrees remain in place until the firm has made the necessary changes and shown that it is capable of producing the quality product(s) in compliance with the regulations. This is often for 1, 2, or 3 years, since many changes must be made and cannot be implemented in a shorter period of time. Invariably, management changes are needed. Consent Decrees are both embarrassing and costly.

If all else fails, the firm can be shut down completely.

The content above describes the purpose and nature of Food and Drug Administration Inspections.

3. Documents Reviewed by JJF

A white loose leaf binder containing 25 tabbed sections was sent to James Farley by The Miller Firm. The binder was labeled "Digitek Documents." The package also contained a letter from Peter A. Miller to James J. Farley dated January 26, 2010. The letter stated that the documents were enclosed. Each tabbed section contained one, or several, documents, related to Actavis Totowa at various sites in the area of Totowa, New Jersey. Other company names mentioned in the set of documents are Mylan Laboratories, Bertek Pharmaceuticals, and Amide Pharmaceuticals.

Additional white loose leaf binders were subsequently received. One was labeled "Supplemental Documents for Digitek Expert James Farley." The last white binder received was labeled. "Supplemental Documents for Digitek Expert James Farley (2)" and had tabbed sections A and B, each of which contained several documents.

The sets of documents contain, among other things, FDA 483s, Warning Letters, Actavis responses, a Consent Decree, and parts of a batch record of Batch 70924A1. The complete list is contained in the section below, "Documents Reviewed by James J. Farley." There are some points to be made regarding the documents. These points are listed as "Notes" before the actual list of documents.

Note 1: Dates of inspections listed by me are the dates the inspections were concluded. They spanned several days that were not necessarily consecutive. Therefore, a single date is used here. In the documents, the range of dates of an inspection is given.

Note 2: There are some cases of seeming duplications of documents. In most of these cases there are different redactions so that, while the titles of the documents are identical, the readable portions are different.

Note 3: The documents in the first big white binder ("Digitek Documents") occupied positions in tabbed sections and are listed as such. Some documents in the various white binders had Plaintiff's Exhibit (PE) numbers while others had no numbers.

Note 4: The date formats are different in different documents, generally in accordance with their formatting in the document that was reviewed.

Note 5: In the "Tab" and "PE" columns the numbers in parentheses ( ) indicate that the document has been listed earlier in the tabulation. There are, in many cases, different redactions of the same document; therefore, all documents, even those with titles that were previously logged in here, were reviewed.

Note 6: Regarding Bates numbers, some documents had them and some did not have them. Of those that had Bates numbers most were legible but some were not legible. The numbers are quoted exactly as on the documents. For example, some began with MYLN and others began with MLYN. Documents are referenced here by binder and tab number, Plaintiff's Exhibit number, and by Bates number, whichever is available to reference any individual document.

Documents Reviewed by James J. Farley

			Big White Binder with Tabbed Sections
Tab	**PE**	**Subject**	**Document**
1		Distributing Agreement	5 August 1999 Mylan/Amide Distributing Agreement [MLYN 000032383 - MLYN 000032445] [63 pages; many numbers illegible]
2		FDA Inspection	Form 483 (Little Falls Facility) 08 Feb 2006 (FOIA Request)
3	68	FDA Inspection	Form 483 (Little Falls Facility) August 10, 2006 (FOIA Request)
4		FDA Warning Letter	15 August 2006 FDA Warning Letter [ACTAV 000028926 - ACTAV 000028928]
5	69	FDA Inspection	17 Nov 2006 Nasrat A. Hakim, Actavis, Response to 8/10/06 Form 483
6		Chronology	Jan 2007 - Mylan PowerPoint - Chronology of Actavis Totowa (formerly Amide) Regulatory Issues [MLYN 000032351 - MLYN 000032359]
7		Quality Systems Improvement Plan (QSIP)	01 Feb 2007 Talbot to FDA
8	25	FDA Warning Letter	01 Feb 2007 Revised Warning Letter [ACTAV 000028242 - ACTAV 000028248] [7 pages; 1 number illegible]
9		Supply Agreement – Mylan Bertek and Amide [sic]	01 Feb 2007 Mylan Primary Manufacturer as per ANDA 6.7(b) [MYLN 000284735]
10		FDA Inspection	05 Sept 2007 483 Little Falls [ACTAV 000028940 ?? - ACTAV 000028943] [4 pages; 2 numbers illegible]
11		FDA Inspection	"Establishment Inspection Report 483" [sic] of 09/05/07
12		Incident Report	Lot 70924 30 Nov 2007 Incident Report [ACTAV 000002757]

13	26	FDA Inspection	483 (Riverview Facility) 20 May 2008 (FOIA Request) [ACTAV 000028225 - ACTAV 000028240]
14		FDA Inspection	"Establishment Inspection Report 48" of 03/18/08
15		FDA Inspection	21 May 2008 Actavis Response to 5/20/2008 FDA 483
16		FDA Inspection	6 June 2008 Actavis Response to 5/20/2008 FDA 483 [ACTAV 0000 ?? - ACTAV 000028824] [5 pages; first number illegible]
17		FDA Inspection	11 June 2008 Actavis Response to 5/20/2008 FDA 483 [ACTAV 001302483 - ACTAV 001302501]
18		FDA Inspection	25 July 2008 Actavis Response to FDA 483
19		FDA Inspection	15 Aug 2008 Actavis Response to 5/20/2008 FDA 483
20		Injunction	US Dept of Justice Complaint for Permanent Injunction
21		Consent Decree	US Dept of Justice Consent Decree of Permanent Injunction
22		Consent Decree	9 Jan 2009 FDA News Release – *FDA Awaits Court's Entry of A Permanent Injunction Against Actavis Totowa, LLC*
23		Timeline	Actavis Totowa LLC Timeline [ACTAV 000309763]
24		Mylan Letter (internal) re: 3rd party manufacturers	03 May 2008 Mylan Quality Agreement Letter
25	16	Deviation Report	Investigation of Deviation Report [various sequential and nonsequential numbers, 67 pages]
			Supplemental Documents White Binder
Tab	**PE**	**Subject**	**Document**
	(26)	FDA Inspection	483 (Riverview Facility) May 20, 2008 [ACTAV 001894428 - ACTAV 001894462]
(2)	79	FDA Inspection	483 (Little Falls Facility) Feb 8, 2006 [ACTAV 0000289 ??] [7 pages; most numbers illegible]

(4)	229	Warning Letter	Douglas Ellsworth, FDA District Director (DD) to Divya Patel Aug 15, 2006 [ACTAV 000923261 - ACTAV 000923264] [4 pages; 1 number illegible]
(3)	68	FDA Inspection	483 (Little Falls Facility) Aug 10, 2006
	90	FDA Inspection	Establishment Inspection Report (EIR) (Little Falls Facility) Aug 10, 2006
	228	FDA Inspection	Letter from Nancy Rolli, FDA Supervisory Inspector to Divya Patel dated Nov 17, 2006 with EIR of October 11, 2006 attached [20 pages; numbers illegible]
(8)	25	Revised Warning Letter	Douglas Ellsworth, FDA District Director (DD) to Divya Patel [ACTAV 000028242 - ACTAV 000028248] [7 pages; 2 numbers illegible]
(10)	50	FDA Inspection	483 (Little Falls Facility) Sept 28, 2007
(11)	158	FDA Inspection	Establishment Inspection Report (EIR) (Little Falls Facility) Sept 28, 2007
	(26)	FDA Inspection	483 (Totowa Facility) May 20, 2008 [ACTAV 000028225 - ACTAV 000028240] [16 pages; 2 numbers cut off but readable]
(14)	91	FDA Inspection	Establishment Inspection Report (EIR) (Totowa Facility) May 20, 2008
	115	Actavis Quality	Mike Adams to Vincent Mancinelli (both of Mylan) dated April 28, 2008 the subject of which is "Discussion with Actavis Quality" [MYLN 000934214]
	106	Actavis internal memo on FDA Little Falls Inspection Closeout	Unsigned. On Actavis letterhead. May 20, 2008 [ACTAV 00054300 ?? - ACTAV 000543004] [4 pages; 1 number illegible]
	221	Actavis Recall Package	Actavis Recall Package for Digitek (Digoxin tablets, USP) 0.125 mg and 0.25 mg. [ACTAV 000028178 - ACTAV 000028222]

	220	Letter – Omega to Actavis	Corporate and Occupational Health Services re: Health Hazard Evaluations of Digoxin tabs 0.125 mg. [ACTAV 000006569] and [ACTAV 000006579 - ACTAV 000006580]
(5)	(69)	Letter – Actavis to FDA	Nasrat Hakim to Andrew Ciaccia, Compliance Officer. Monthly Update.
(20)	82	Complaint for Permanent Injunction	U S Dept of Justice (DOJ) v. Actavis Totowa LLC.
(21)	214	Consent Decree of Permanent Injunction	U S District Court, District of New Jersey. Civil Action No. 08-cv-05656 Hon. Susan D. Wigenton
(6)	233	Chronology of Actavis Regulatory Issues	Chuck Koon, Mylan, to Patricia Latzo, Mylan [MLYN 000032351 - MLYN 000032359]
	234	Chronology of Actavis Regulatory Issues	Chronological Tabulation [MYLN 00001668 ??] [number illegible]
	136	Mylan audit	Report of audit of Actavis. Pinnell and Streater [5 pages; numbers illegible]
	147	Actavis e-mail	Phyllis Lambridis, V P U S Quality & Compliance to Jacob Haroon, then to Jasmine Shah. Contains May 20, 2008 Totowa facility 483 [ACTAV 000500876 - ACTAV 000500892]
	235	Amide's FDA inspectional history	Amide's FDA inspectional history March 23, 1992 – March 31, 2004 Author unknown [ACTAV 001087612 - ?] [10 pages; most numbers illegible]
		Jasmine Shah deposition	Former Actavis U S V P for Regulatory and Medical Affairs

			Supplemental White Binder (2) containing Tab A and Tab B sections
			Tab A section. Responses.
Tab	**PE**	**Subject**	**Document**
		483 Response letter.	483 response, Divya Patel to Douglas Ellsworth dated August 29, 2006 [ACTAV 000511447 - ACTAV 000511481]
		Warning Letter 06-NWJ-15 response.	Response, dated September 6, 2006, to August 15, 2006 Warning Letter 06-NWJ-15, Divya Patel to Sara A. Della Fave at FDA, copy to Douglas Ellsworth at FDA [ACTAV 000028929 - ACTAV 000028933]
		FDA response to D. Patel's Warning Letter 06-NWJ-15 response.	FDA to Divya Patel regarding his responses to the August 15, 2006 Warning Letter 06-NWJ-15 [ACTAV 00002884 ?? - ACTAV 000028849] [4 pages; 2 numbers illegible]
		483 Response letter.	Response, dated June 6, 2008 to the 483 dated May 21, 2008, Phyllis Lambridis, Actavis' V P U S Quality Assurance to Douglas Ellsworth at FDA
		483 Response letter.	Letter dated May 21, 2008, from Sigudur Oli Olafsson, Deputy CEO Actavis Group to Douglas Ellsworth, District Director, FDA.
		483 Response letter.	Letter dated June 11, 2008, from Sigudur Oli Olafsson, Deputy CEO Actavis Group to Douglas Ellsworth District Director, FDA. Signed by Phyllis Lambridis for Sigurdur Oli Olafsson.
		483 Response letter.	Letter dated June 20, 2008, from Sigudur Oli Olafsson, Deputy CEO Actavis Group to Douglas Ellsworth, District Director, FDA. [ACTAV 00002827 ??] [19 pages; numbers illegible] and [ACTAV 000296189 - ACTAV 000296190]
		483 Response letter.	Letter dated July 25, 2008, from Sigudur Oli Olafsson, Deputy CEO Actavis Group to Diana Amador-Toro, Acting District Director, FDA. Signed by Phyllis Lambridis for Sigurdur Oli Olafsson.

		483 Response letter. Response to follow-up questions on 483 responses.	Letter dated August 15, 2008, from Anthony J. Delicato, Director, Quality Assurance, Actavis Group to Ms. Sarah A. Della Fave, Compliance Officer, FDA.
			Tab B section. OOS Documents
Tab	**PE**	**Subject**	**Document**
	241	Out - of - Specification (OOS) Digoxin Tablets 0.25 [mg?]	Letter dated June 8, 2004, from Jasmine Shah, Amide, to Amin Nanji at Rite Aid Pharmacy. Subject is Thick Digoxin Tablets, 0.25 mg. [ACTAV 001316391]
	128	Out - of - Specification (OOS) Digoxin Tablets 0.25 [mg?]	Amide Investigation Report with initiation date 7/9/04. Subject is Thick Digoxin Tablets. [ACTAV 001375829 - ACTAV 001375833]
	242	Out - of - Specification (OOS) Digoxin Tablets 0.25 [mg?]	Letter dated July 13, 2004, from Jasmine Shah, Amide, to Amin Nanji at Rite Aid Pharmacy. Subject is Thick Digoxin Tablets. [ACTAV 001316392]
	261	Content Unifomity of a batch of Digoxin Tablets 0.125 mg.	Memo dated January 13, 2007, from Daniel Bitler, Actavis to Investigation OOSN06-014. Subject is "...Product Disposition of Batch 60992A." [ACTAV 000023139 - ACTAV 000023147]
	133	Status Report [on batch record reviews?]	e-mail dated September 27, 2007, from Scott Talbot, Actavis to Jasmine Shah and others. Subject: Status Report. [ACTAV 001420145 - ACTAV 001420151]
	44	Incident Report	Incident Report. Control number 70924A1, prepared by Packaging Manager (Delip Joshi?). Subject is two Digoxin tablets 0.125 mg were found with approximately double thickness. [ACTAV 000002757]
	172	Chromatographic and release data.	e-mail on March 19, 2008 from Jisheng Zhu to Elina Novikov, in response to her e-mail. [ACTAV 000174387]

	143	Digitek batches on HOLD	e-mail on April 2, 2008 from Suzanna Wolfe to Janet Kinsley, both of Mylan, in response to her e-mail. [MYLN 000032816 - MYLN 000032817]
	217	List of investigations by product	e-mail dated April 15, 2008, from Misbah Sherwani, Actavis to "blank field". Subject: List by Product [ACTAV 000299883] [7 pages; most numbers illegible]
	159	Blend failure investigation	Blend Failure Investigation. Printed names are Leroy Lundner and Scott Talbot. No signatures or dates. [ACTAV 000165623 - ACTAV 000165630]
	63	High or low weight tablets. "Digitek 0.125 mg. lot # 80228A1"	Series of e-mails on February 25, 2009 from Lisa Bennet, Paul Galea, and Danielle Comrie – individually.
		"double thick tablet"	e-mail on April 30, 2008 from Jennifer Urso of Pharmacy Services Golden Living Clinical Services to Jill Abraham at Mylan Labs – individually. [MYLN 000932683]
			White Binder labeled "Depositions of Phyllis A. Lambridis and Wanda Eng
Tab	**PE**	**Subject**	**Document**
		Phyllis A. Lambridis deposition	Phyllis A. Lambridis deposition of January 18, 2010
		Wanda Eng deposition	Wanda Eng deposition of January 28, 2010
			White Binder labeled "Deposition of Phyllis A. Lambridis, also Plantiff's Exhibits 105 through 124
Tab	**PE**	**Subject**	**Document**
		Phyllis A. Lambridis deposition	Phyllis A. Lambridis deposition of January 18, 2010
	105	Phyllis Lambridis's Career Summary	Phyllis Lambridis's Career Summary

	(106)	Actavis Internal Memo on FDA Little Falls Inspection Closeout	FDA Little Falls Inspection Closeout An Actavis Document, dated May 20, 2008 [ACTAV 00054300 ?? - ACTAV 000543004] [4 pages; 1 number illegible]
	107	Digoxin	e-mail Phyllis Lambridis to Chris Young dated April 9, 2008 [ACTAV 000292438 - ACTAV 000292439]
	108	Actavis Totowa Corrective Action Plan	Actavis Totowa Corrective Action Plan, Status Report dated August 28, 2008 [ACTAV 000918567 - ACTAV 000918577]
	109	Product list	e-mail Divya Patel to Kevin Anderson dated April 11, 2008 [ACTAV 00047589 ??]
	110	Organization Charts - Actavis	Organization Charts - Actavis (undated) [ACTAV 000542861 - ACTAV 000542865]
	111	Offer to help	e-mail Tony Castellazzo to Phyllis Lambridis March 17, 2008 [ACTAV 000609594 - ACTAV 000609596]
	112	Totowa FDA Audit	Totowa FDA Audit - set of charts and tables [ACTAV 001863647 - ACTAV 001863683]
	113	Actavis – Digitek drug recall letter	Actavis – Digitek drug recall letter – Phyllis Lambridis – April 24, 2008 [ACTAV 000526961 - ACTAV 000526969]
	114	Stopping Digoxin Production	e-mail Phyllis Lambridis to Bitler, Anderson, and others dated April 30, 2008 [ACTAV 000142150 - ACTAV 000142151]
	(115)	Halted production at Totowa facility	Memo Mike Adams to Vincent Mancinelli dated April 28, 2008 [ACTAV 000934214]
	116	Assessment meetings	e-mail Anthony Castellazzo to many people, dated August 14, 2008 Subject is Assessment Meetings [ACTAV 0003024 ??]

	117	"GMP Storm Cloud"	Phyllis Lambridis to Misbah Sherwani, dated August 13, 2008 Subject is GMP Storm Cloud [ACTAV 000527229 - ACTAV 000527231]
	118	Various quality issues	e-mail Phyllis Lambridis to Tony Delicato dated September 16, 2008 [ACTAV 001267772]
	119	Deviations and CAPA report	November 2008 Monthly Deviations and CAPA Data. [ACTAV 000309296 - ACTAV 000309305]
	120	Actavis – Digitek drug recall letter	Actavis – Digitek drug recall letter – Phyllis Lambridis – April 28, 2008 [UDLL 000004006 - UDLL 000004008]
	121	Completely redacted, unidentified document	Two completely redacted pages of an unidentified document [ACTAV 001472833 - ACTAV 001472834]
	122	Tabulation of investigations.	Set of tables and charts of investigations [ACTAV 001423183 - ACTAV 001423220]
	123	FDA refusal to permit Changes Being Effected in Zero Days.	e-mail from Rahana Hussain to several persons dated April 14, 2008 Subject is FDA Communications [ACTAV 001423939 - ACTAV 001423942]
	124	Defines adulterated drugs	Section of the U S Code 351 Adulterated Drugs and Devices. TITLE 21 > CHAPTER 9 > SUBCHAPTER V > Part A > § 351
			This is the end of the Document Section.

4. Additional Reference Sources

- The United States Food, Drug, and Cosmetic Act
- Title 21 of The Code of Federal Regulations, primarily parts 211 (cited 21CFR211) and 7, and other parts
- *The Physician's Desk Reference, PDR*, 63rd edition, Year 2009
- *The Merck Index*
- The FDA Investigations Operations Manual (IOM)

- The FDA Compliance Program Guidance Manual, 7356.002
- The FDA Guidance for Industry - Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production, October 2006
- The FDA Guide to Inspections of Dosage Form Drug Manufacturer's CGMPRs (Current Good Manufacturing Procedure Regulations), October 1993.

5. Comments

While the reviews of all the documents listed in the table above provided for the evaluation of the regulatory status of Actavis Totawa, the comments below, some with excerpts, will provide examples of why the conclusions were not only formulated but were readily apparent.

A- Undated and unsigned correspondence from Actavis relating to the "Little Falls Inspection Closeout – May 20, 2008" (Plaintiff's #106) contains such comments as "...from a Quality Systems standpoint there was 'Total Failure'..." and "... there is a need for... Improved Infrastructure, Personnel, and a Philosophical Shift" and "Robert Wessman [Executive Chairman Actavis U S] agreed that the Little Falls site needs new systems and experienced personnel" and "...48 products with no impurity profile." To have a "total failure" such as this indicates that there is no product of this company at that location that can be relied upon to be of the proper "Identity, Strength, Quality, and Purity" acceptable to the FDA as being safe for the consumer.

B- Quoting from page 8 of the Complaint for Permanent Injunction which is in Tab 20, (also as Plaintiff's #82), "...FDA conducted another inspection of Actavis Totowa's Little Falls facility and observed numerous CGMP deficiencies that were the same or similar to observations from the previous inspection...." This leads any responsible person to ask the question: "Why didn't they fix what was broken?"

C- The United States, through the Consent Decree (Plaintiff's #214), instructs Actavis Totowa (page 6, Section 4 C) to engage the services of an independent expert – the GMP Expert – to determine whether the methods, facilities, and controls conform to GMPs. This is usually a consulting firm and many consultants are required to function as a team to bring the company into compliance. This is done because it is recognized that the company is not capable of bringing itself into compliance. It is done when a product is needed by the public but the firm can't produce the necessary quality on its own, and therefore, a third party (a consulting firm) guides the company in the manufacturing and testing of its products. It is embarrassing and costly.

D- Regarding Product Recalls - Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. When done at the request of the FDA such a recall is still considered voluntary. However, if the firm does not recall the product as the FDA requested it to do, the FDA will usually, as a next step to protect the consumer, employ the actions of Seizure or Injunction against the firm. The FDA does not recall products. It requests the manufacturer to recall the products. The manufacturer or distributor does this and therefore it can be called a

voluntary recall. Additionally, a Class I recall is employed in a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. Class II and Class III recalls are important yet are employed where the probability of serious adverse health consequences is remote. Class I was employed in this case.

E- Fact versus Opinion. The FDA 483 contains a list of observations which are violations of the regulations. Inspectors and scientists are trained to list only facts and not opinions on the document.

A fact is listed and then examples are provided. No opinions are to be on a 483. (The underlines in this section are by James Farley)

The FDA Investigations Operations Manual (IOM) states, in **section 5.2.3.2, Reportable Observations**, "You should cite factual observations of significant deviations from the FD&C Act…"

The FDA Investigations Operations Manual (IOM) states, in **section 5.2.3.2.1, Adulteration Observations**, "Include specific factual observations…"

The FDA Investigations Operations Manual (IOM) states, in **section 5.2.3.2.2, Other Observations**, "You may include other factual observations of significant deviations from the FD&C Act…"

The FDA Investigations Operations Manual (IOM) states, in **section 5.2.3.3, Non-Reportable Observations**, "Do not report opinions, conclusions, or characterize conditions as 'violative.' The determination of whether any condition is violative is an agency decision made after considering all circumstances, facts and evidence."

F- In the Federal Food, Drug, and Cosmetic Act, specifically, **Sec. 501. [21 USC §351] Adulterated Drugs and Devices**, it is stated that "A drug or device shall be deemed to be adulterated…if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess…." Therefore, since the Actavis facility was determined to be in violation of (not in compliance with) good manufacturing practices, GMPs, the drugs that were produced were adulterated. Additionally, since the non-compliance problem was systemic, all products, including Digitek, were adulterated.

G- Blend Uniformity. In the FDA 483 dated May 20, 2008 (Plaintiff's Exhibit #26) Observation 4 mentions blend uniformity problems. 4a mentions out-of-specification results for blend uniformity for Digoxin Tablets 0.125 mg. 4c mentions "…approximately [redacted] products were 'temporarily discontinued' due to blend uniformity and/or content uniformity issues…." Blend uniformity refers to the blended material before pressing into tablet form. Content uniformity means the uniformity of individual tablets, that is, the uniformity of the amount of active ingredient measured tablet to tablet. This is extremely important with Digoxin since the

active ingredient is theoretically present to the extent of 0.125 milligram (mg) in a tablet weighing 105.000 milligrams. That is 1.2 parts active ingredient per 1000 parts total tablet weight. Proper blending is very important here. In comparison, a 200 mg strength Advil (ibuprofen) tablet contains 200.0 mgs active ingredient per total tablet weight of 528.0 mgs which is 378 parts active ingredient per 1000 parts total tablet weight. Another example is the 10 mg strength Lipitor (Atorvastatin Calcium) which contains 10.0 mgs active ingredient per total tablet weight of 152.0 mgs. This is 65 parts active ingredient per 1000 parts total tablet weight.

6. Conclusions

My conclusions are based on my knowledge and experience of the pharmaceutical industry, being employed in the industry being regulated, working at the FDA, which is the regulator, and the last 14 years as a pharmaceutical and FDA regulatory consultant. My experience is detailed at the beginning of this report as **"1. Qualifications"**.

Based on the review of the documents listed in this report I conclude that Actavis had essentially no quality control over the products it produced and shipped. There are violations in the areas of Adverse Event reporting, Out - of - Specification (OOS) investigations, Deviation investigations, the Corrective Action; Preventive Action (CAPA) program, and various GMP areas. All of these are shown to recur thereby indicating that no corrective actions were made.

There are many Good Manufacturing Practice (GMP) infractions that recur. This should not be the case with any pharmaceutical firm. Once an infraction is noted as an "Observation" on any FDA form 483 it should be addressed and corrected. To not correct an infraction is to either not care or be unable to comply, or both. Quoting from the Complaint for Permanent Injunction which is in Tab 20, "...FDA conducted another inspection of Actavis Totowa's Little Falls facility and observed numerous CGMP deficiencies that were the same or similar to observations from the previous inspection...."

To be under a Consent Decree for more that 10 consecutive years is an indication of continuing serious problems with FDA regulations. The history of the company from Amide through Actavis Totowa is a series of FDA regulatory problems from "483s" to Warning Letters to the longstanding Consent Decree, all of which indicate varying degrees of non-compliance with FDA regulations and show the inability to produce products that meet the standards necessary to ensure safety for the consumer.

The problems at Actavis are systemic. That is, they are part of the actual operation of the company in its attitude and in its production of drugs for consumers. When such problems are systemic they are based in the management of the company. Changes are needed by or within Actavis management structure to correct the situation and bring the company into compliance with FDA regulations, and to ensure that safe, quality products are manufactured. Since the non-compliance problem was systemic, all products, including Digitek, were adulterated as defined in Section 501 of the Food, Drug, and Cosmetic Act.

Patients have no assurance of the proper quality of the Actavis products since many were produced under non-compliant conditions in violation of FDA regulations.

James J Farley June 14, 2010

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June 14, 2010